REMARKS

Claims 1, 3-8, 21 and 35-38 are pending. No new matter has been added by way of the present amendments. For instance, claim 1 has been amended to correct a minor formality. Claims 5 and 6 are amended to insert an amount of protective antigen protected by the 67 kDa protein. This amendment is supported by the description of Figure 6 at page 4 of the specification. Claim 6 has been amended to delete "partially". Newly added claim 35 is supported by claim 21. Newly added claim 36 is supported by the present specification, for instance the Examples. Newly added claim 37 is supported by the present specification, for instance the Examples. Lastly, newly added claim 38 is supported by claim 1, limitation (ix). Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 1, 3-8 and 21 under 35 U.S.C. §112, first paragraph for the reasons recited at pages 2-9 of the outstanding Office Action. Applicants respectfully traverse.

1. Written Description Issue

The Examiner has asserted that the present specification only provides written description for the 67-kDa protein isolated from *Imperata cylindrical*. Applicants respectfully disagree. In particular, although the 67 kDa protein was isolated from *Imperata cylindrical*, a similar protein was demonstrated in *Lolium perenne, Phleum pratense* and *Cynodon dactylon* using patients' sera specific to these grasses. The Examiner is requested to consult the present specification, for

instance, at page 8, lines 11-14, page 9, lines 26-30 and the Examples. In particular, Applicants direct the Examiner to review Figure 3 showing immunoblot and ELISA tests of extracts from the named plants using serum from allergic patients, showing the presence of a 67 kDa IgE binding protein. This is evidence that the 67 kDa type protein is present in these grass extracts and therefore show reactivity by Western blot. This is a very sensitive and specific procedure that confirms a similar kind of protein present in these extracts. This data provides the requisite proof that Applicants possessed the 67 kDa protein not only from *Imperata cylindrical*, but also *Lolium perenne, Phleum pratense* and *Cynodon dactylon.*

Applicants again stress that the Examiner, without shifting the burden of proof to Applicants, cannot require the present claims to be limited to subject matter that has actually been reduced to practice. It is not the law that an Applicant must restrict his claims to working examples actually reduced to practice. *See, e.g. In re Rasmussen,* 221 USPQ 323 (CCPA 1981); *In re Koller, Hartl & Kirchner,* 204 USPQ 702 (CCPA 1980). Indeed working examples are not at all required for a disclosure to adequately support a claim. *In re Strahilevitz*, 212 USPQ 561 (CCPA 1982).

Applicants also stress that the invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112, first paragraph. *In re Lukach et al.*, 169 USPQ 795, 796 (CCPA 1971). To satisfy the written description requirement of 35 U.S.C. §112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Simply put, a patent specification must contain a written description of the invention

sufficient to "allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Gentry Gallery, Inc. v. Berkline Corp.*, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998) (quoting *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)).

Based upon the above alone, Applicant submit that those of skill in the art would understand that Applicants were in possession of the subject matter claimed at the time of filing. Thus, there exists no written description issue with respect to the type of grass from which the protein is obtained.

Further, Applicants submit that in addition to being incorrect, the Examiner has not shifted the burden of proof to Applicants. Insofar as the written description requirement is concerned, that burden is discharged by "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *In re Wertheim et al.*, 191 USPQ 90, 97 (CCPA 1976). That is, if the specification contains a description of the claimed invention, albeit not *in ipsis verbis*, then the examiner or Board, in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient. *Id.* at 98.

To summarize, Applicants submit that those of skill in the art would understand that Applicants were in possession of the claimed subject matter at the time of filing. Alternatively, the Examiner has failed to shift the burden of proof to Applicants. In any event, the outstanding rejection is improper and should be withdrawn.

2. Enablement Issue

The Examiner has also asserted that there is no evidence provided that the present 67-kDa protein can treat anthrax exposure *in vivo*. Applicants respectfully traverse this enablement

rejection and submit that it is not necessary to provide such a showing in view of the detailed evidence already of record.

Applicants are required to present a specification that establishes, by a preponderance of the evidence (not beyond reasonable doubt or even clear and convincing evidence) that the protein in question would have the utility asserted such that the use of the invention is enabled. It is contrary to the intent of the patent laws to require complete reduction to practice of therapeutic use, i.e. an example of actual therapy, as such would delay disclosure of the invention, rather than promote it. *See, In re Bundy,* 209 USPQ 48 (CCPA 1981).

To this end, Applicants respectfully submit that the present specification demonstrates that the present protein is able to inhibit anthrax toxin *in vitro*. Furthermore, the *in vitro* test is one performed on cultured cells in the presence of blood serum proteins (see Example 7). In fact, this tissue culture experiment is similar to *in vivo* treatment and can be extrapolated thereto. It clearly indicates that the 67-kDa protein blocks the entry of anthrax toxin and that a higher number of cells survived toxin exposure due to this treatment. This clearly illustrates that the 67-kDa protein is effective in reducing the cleavage of anthrax toxin protective antigen, thereby enhancing cell survival.

More specifically, the function of 67-kDa protein is to inhibit the cleavage of anthrax toxin. To prevent the cleavage of anthrax toxin protective antigen, before the start of the experiment the cells were pre-incubated with the 67-kDa protein. Such will be effective *in vivo* because *Bacillus anthrax* secretes both toxin components individually and so cleavage of the protective antigen toxin component can thus be inhibited. In a similar manner Applicants have

conducted an experiment where they have incubated both protective antigen and the 67-kDa protein together and the 67-kDa protein has inhibited anthrax toxin activity.

Therefore, the present specification provides those of skill in the art with the requisite teachings. For instance, evidence is already on the record that the protein of the invention can likely retain its activity in circulation, and is therefore effective in preventing anthrax toxicity to mammalian cells.

Moreover, the present 67 kDa protein is also an allergen and treatment of allergy can be performed by immunotherapy using this protein. Immunotherapy is the process similar to vaccination. Hence, the blocking antibodies generated by this protein will protect the individuals from allergic reactions to grasses.

Applicants further address the Examiner's comments at page 8, second to last paragraph of the outstanding Office Action where the Examiner asserts that the 67-kDa protein is not a "protected antigen." Applicants respectfully submit that a protective antigen is the name of the anthrax protein, which on cleavage allows lethal factor or edema factor to bind and thereby these proteins enter the cells to give bio-chemical activity. Applicants again emphasize that the 67-kDa protein inhibits the activity of anthrax toxin protective antigen thereby the enzymatic proteins (LF or EF) are not delivered to the cytosol of the cells.

Based upon the above, it is evident that those of skill in the art are able, without undue experimentation, to practice the presently claimed subject matter. As such, the Examiner is respectfully requested to withdraw the enablement rejection under 35 U.S.C. §112, first paragraph.

Issues under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1, 3-8 and 21 under 35 U.S.C. §112, second paragraph for the reasons recited at page 16 of the outstanding Office Action. Applicants respectfully traverse these rejections.

First, the Examiner asserts that claim 1 is unclear with respect to the recitation of language such as "the genus related to." Applicants respectfully traverse and submit that those of skill in the art understand the metes and bounds of such language. Although these phrases may arguably be broad, it is not indefinite. Applicants respectfully submit that the second paragraph of 35 U.S.C. §112, requires that the claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Nowhere within the statute is there an explicit recitation that the scope of the claim, whether it is broad or narrow, adversely effects the distinctness of the claimed subject matter. Furthermore, the MPEP states:

> Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. (see MPEP §2173.04).

As such, Applicants respectfully submit that the rejection of the phrase "the genus related to" under 35 U.S.C. § 112, second paragraph is improper.

Second, the Examiner has rejected claim 6 asserting that the phrase "partially inhibits" is unclear. Applicants traverse and submit that claim 6 has been amended to delete the word "partially." This is a non-narrowing amendment which renders this rejection moot.

In view of the above, Applicants submit the present claims fully satisfy the requirements of 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal thereof are respectfully requested.

Issues under 35 U.S.C. §102(a)

The Examiner has maintained the rejection of claims 1, 3-8 and 21 under 35 U.S.C. §102(a) as being anticipated by Bijli et al (Clin. Exp. Allergy, January 2003) (hereinafter "Bijli 2003"). Applicants respectfully traverse.

The presently rejected claims all require that the protein be "isolated." However, Applicants respectfully submit that in the paper of Bijli 2003 (page 65) the protein was not isolated but only observed with SDS-PAGE. There was simply no protein purification in Bijli 2003. Therefore, the activity of the purified protein has not been shown by Bijli 2003. Bijli 2003 describes that after keeping the *Imperata* extracts with different stabilizers, the protein could maintain the allergenic activity in the extract. The protein may be a mixture of proteins or degradation products of high molecular weight proteins. Regardless, no protein is isolated in Bijli 2003 and thus there can be no anticipation.

Moreover, there is no evidence that all of the characteristics recited in claim 1 are achieved by Bijli 2003. The Examiner urges a side-by-side comparison, however, this is not necessary. First, Bijli 2003 does not "isolate" a protein. Second, there is no evidence that any protein achieved by Bijli 2003 inherently achieves the presently claimed limitations. A theory of inherency must be supported by facts and/or technical reasoning that reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy* 17 USPQ2d 1461 (BPAI 1990) (emphasis added). In order for

prior art to anticipate a claimed compound on the ground it is inherently produced in a prior art process, the inherency must be certain. *Glaxo, Inc. v. Novopharm Ltd.,* (EDNC 1993) 830 F. Supp 871, 29 USPQ2d 1126; *Ex parte Cyba* (POBA 1966) 155 USPQ 756; *Ex parte McQueen* (POBA 1958) 123 USPQ 37. The fact that a prior art article may inherently have the characteristics of the claimed product is not sufficient. *Ex parte Skinner* (BPAI 1986) 2 USPQ2d 1788. Inherency must be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 666 F2d 578, 212 USPQ 323; *Ex parte Keith et al.* (POBA 1966) 154 USPQ 320.

In the present instance, such evidence simply does not exist to support a theory of inherency. As such, there can be no anticipation of the rejected claims. Reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. §102(b)

The Examiner has also rejected claims 1-8 and 21 (Applicants note that claim 2 is cancelled) under 35 U.S.C. §102(b) as being anticipated by Bijli et al. (Journal of Immunological Methods 260 (Feb. 2002, 91-96) (hereinafter referred to as "Bijli 2002"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that the reference of Bijli 2002 (page 92-93) fails to teach that a 67 kDa protein is isolated from *Imperata.* Bijli 2002 argues that a protein(s) or degraded protein of higher molecular weight separates around the same molecular weight. The protein was never isolated and never confirmed to be the same as that presently claimed. As such, Applicants submit that there is no anticipation of the present claims. Reconsideration and withdrawal of this rejection are respectfully requested.

Lastly, the Examiner has rejected claims 1-8 and 21 (note that claim 2 is cancelled) under 35 U.S.C. §102(b) as being anticipated by Verma et al. (International Archives of Allergy and Immunology, 2000, 122:251-256) (hereinafter referred to as "Verma"). Applicants respectfully traverse.

Applicant submit that the protein isolated by Verma is different from that isolated in the present invention. Evidence of this point is the fact that Verma asserts that this protein cannot be sequenced (see Declaration under 37 C.F.R. §1.132 submitted on February 6, 2006). In contrast, as previously shown on the record, the present protein can be sequenced using Edman degradation. Verma purify their protein to a single band by SDS-PAGE analysis using ion exchange chromatography, and find that the amino terminus is blocked and consequently no sequence was obtained. *See,* the legend to Figure 1 (purification) and the top of column 1 on page 255 (sequencing result). It is evident that the properties of the respective proteins of Verma and the present invention differ and therefore they cannot be the same proteins. Thus, it is evident that there is no anticipation based upon Verma. Reconsideration and withdrawal of this rejection are therefore respectfully.

In view of the above, Applicants respectfully submit that the present claims define allowable subject matter. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact the undersigned at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for

any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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